

PETITION FOR EXTENSION OF TIME

Applicants hereby request a one-month extension of time extending the time for response from January 7, 1997 up to and including February 7, 1997. The Assistant Commissioner is hereby authorized to charge the required \$110.00 fee to Deposit Account No. 23-1703. Any additional fees due in connection with this Petition should likewise be charged.

Please amend the application as follows:

In the Claims:

J1
~~18~~ 17. (twice amended) [A] The method [for the treatment of asthma and other inflammatory respiratory disorders, which comprises administering by inhalation to a host in need of such treatment effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide] according to claim ¹⁷~~7~~, wherein the effective amount of the physiologically acceptable salt of formoterol or solvate thereof is 6-100 µg per day, and the effective amount of budesonide is 50-4800 µg per day.

[Please add the following new claims:

J2
~~26~~ 29. The method according to any one of claims ¹⁷~~7~~, ¹⁸~~17~~ and ¹⁹~~18~~, wherein the physiologically acceptable salt of

formoterol or the solvate thereof is administered in admixture with the budesonide.

⁹~~30~~. A medicament containing as active ingredients effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:1 to 1:60.

¹²~~31~~. A pharmaceutical composition which comprises effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:1 to 1:60, together with a pharmaceutically acceptable carrier.

²⁷~~32~~. A method for the treatment of asthma and other inflammatory respiratory disorders which comprises administering by inhalation to a host in need of such treatment effective amounts of a physiologically acceptable salt of formoterol or a solvate thereof, and budesonide wherein the molar ratio of the formoterol component to the budesonide component is in the range from 1:1 to 1:60.

¹⁰~~33~~. The medicament of claim ⁹~~30~~ wherein the active ingredients are in dry powder form.

¹¹~~34~~. The medicament of claim ⁹~~30~~ or ¹⁰~~33~~ wherein the formoterol is in the form of the fumarate dihydrate.

¹³
~~35~~ 35. The pharmaceutical composition of claim ¹²~~31~~
wherein the formoterol is in the form of the fumarate
dihydrate.

²⁸
~~36~~ 36. The method according to claim ²⁷~~32~~, wherein the
effective amount of the physiologically acceptable salt of
formoterol or solvate thereof is 6-100 μg per day, and the
effective amount of budesonide is 50-4800 μg per day.

²⁹
~~37~~ 37. The method according to claim ³⁸~~36~~ wherein the
effective amount of the physiologically acceptable salt of
formoterol or solvate thereof is 6-48 μg per day, and the
effective amount of budesonide is 100-1600 μg per day.

³⁰
~~38~~ 38. The method according to any one of claims ²⁷~~32~~, ²⁸~~36~~
and 37 wherein the administration is performed from a dry
powder inhaler.

³¹
~~39~~ 39. The method according to claim ³⁰~~38~~ wherein the
inhaler is a Turbuhaler™.

³²
~~40~~ 40. The method according to any one of claims ²⁷~~32~~, ²⁸~~36~~
and ²⁹~~37~~ wherein the administration is performed from a
metered dose inhaler.

³³
~~41~~ 41. The method according to any one of claims ²⁷~~32~~, ²⁸~~36~~
and ²⁹~~37~~ wherein the formoterol is in the form of the
fumarate dihydrate.

¹⁴
~~42~~ 42. A pharmaceutical composition according to claim
¹²~~31~~ wherein the pharmaceutically acceptable carrier is
lactose.